US ERA ARCHIVE DOCUMENT

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - II

Antimicrobial Program Branch

EPA Peti	tion or File S	ymbol 113	10-6	<u> </u>	and the second of the second o
Date Div	vision Received	07-	-21-88		
MRID Nos	403839-01,	403839-02,	406352-01 &	407493-01	to 407493-04
Product	Manager	31	(Lee)		
Product Name_		Bur	Burnishine® Germicidal Cloth		
Company Name			Burnishine Products		

202.0 Recommendations

202.1 Efficacy Supported By The Data

- a. The submitted data are adequate to support effectiveness of the product as a "one-step" cleaner-disinfectant for hospital/general use against Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa in the presence of moderate amounts of organic soil (5% blood serum) on hard, non-porous surfaces which are thoroughly wet by the towelette and remain wet for a contact time of 5 minutes for a single use.
- b. The submitted data are adequate to support effectiveness of the product as a tuberculocide against Mycobacterium bovis in the presence of moderate amounts of organic soil (5% blood serum) on hard, non-porous surfaces which are thoroughly wet by the towelette and remain wet for a contact time of 10 minutes at 20°C for a single use. However, varification must be provided to show that confirmatory tuberculocidal tests were performed in the presence of 5% blood serum.
- c. The submitted data are adequate to support effectiveness of the product as a virucide against Herpes Simplex Type 2 and Influenza A2/Hong kong in the presence of moderate amounts of organic soil (10% Fetal bovine serum) on hard, non-porous surfaces which are thoroughly wet by the towelette and remain wet for a contact time of 30 seconds for a single use.
- d. The submitted data are adequate to support effectiveness of the product as a virucide against Poliovirus-1 in the presence of moderate amounts of organic soil (10% Fetal bovine serum) on hard, non-porous surfaces which are thoroughly wet by the towelette and remain wet for a contact time of 3 minutes for a single use.

203.0 Labeling

a. For tuberculocidal claim wording must be provided to specify that the product is "Effective in 10 minutes at 20°C".